

**REMARKS****Introduction**

Receipt of a non-final office action dated June 3, 2008 is acknowledged. In the action, the claims are rejected allegedly for non-enablement and indefiniteness (claims 55-56, 58 and 60-80), lack of novelty in view of US Patent No. 5,888,510 ("510 patent") (claim 58), Nishimoto *et al.* (claim 58), EP 1074268 (claim 58), and obviousness reasons over Choy *et al.* (2002)(claims 55-56, 58, 61-63, 68-71, 73-74 and 76-80) and Choy *et al.* in view of US Patent No. 5,530,101 ("101 patent") (claims 55-56, 58, 61-63, 66, 68-71, 73-74 and 76-80).

**Status of the Claims**

In this response, applicants amended claim 55 and cancelled all other claims. Support for the amended claim can be found throughout the specification, and in the originally filed claims. Upon entry of this amendment, claim 55 will be under examination.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

It is acknowledged that the foregoing amendments are submitted after final rejection. However, because the amendments do not introduce new matter or raise new issues, and because the amendments either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**Rejection of the Claims Under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph**

Claims 55-56, 58, 61-71, 73-74 and 76-83 are rejected under 35 U.S.C. § 112 for non-enablement. The examiner, however, notes that the specification is "enabling for a method for treating rheumatoid arthritis comprising administering and IL-6 receptor antibody and an

immunosuppressant, wherein the antibody used is a monoclonal antibody PM-1 or MR16-1 . . .” Office action at 3.

In the interest of expediting prosecution, and without acquiescing to the Office’s rejection, applicants cancelled claims 56-83 and amended claim 55 to recite a method for treating rheumatoid arthritis, comprising administering an effective amount of an anti-IL-6 receptor antibody and an effective amount of methotrexate, wherein the anti-IL-6 receptor antibody is a humanized PM-1 antibody. Applicants trust this amendment addresses the Office’s concerns.

**Rejection of the Claims Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph**

Claims 55-56, 58, 61-71, 73-74 and 76-83 are rejected as allegedly indefinite. In the interest of expediting prosecution, and without acquiescing to the Office’s rejection, applicants cancelled claims 56-83 and amended claim 55 to more clearly recite the presently claimed invention.

Applicants trust this amendment addresses the Office’s concerns.

**Rejection of the Claims Under 35 U.S.C. § 102**

Claim 58 is rejected under 35 U.S.C. § 102(b) as allegedly anticipated by the ’510 patent, Nishimoto *et al.*, or EP 1074268. In the interest of expediting prosecution, and without acquiescing to the Office’s rejection, applicants cancelled claim 58, thereby rendering these rejections moot.

**Rejection of the Claims Under 35 U.S.C. § 103**

Claims 55-56, 58, 61-63, 68-71, 73-74 and 76-80 are rejected as allegedly obvious over Choy (2002). In particular, the Office is of the view that the Choy *et al.* reference describes an IL-6 receptor antibody and an immunosuppressant, and therefore the present invention is obvious. Applicants respectfully disagree.

Choy *et al.* describes administration of an anti-IL-6 receptor antibody to a patient to whom prednisolone, which is an oral steroid, had been administered. See page 3144, the right

column, line 13, which states “[c]oncomitant oral steroid treatment was permitted if the dosage was  $\leq 7.5$  mg of prednisolone daily and remained unchanged throughout the study.”

In addition, Choy *et al.* states on page 3144, the right column, line 11, that “[u]se of parenteral and/or intraarticular steroids, immunosuppressants, investigational drugs, and oral anticoagulant drugs within 4 weeks before administration of the study medication was not permitted”, meaning that administration of drugs other than oral steroids (e.g., parenteral steroid, immunosuppressant, etc.) was prohibited.

Accordingly, not only does Choy *et al.* not describe or suggest the combined use of an immunosuppressant and an anti-IL-6 receptor antibody, but the reference also teaches away from the present invention. It should be noted that methotrexate is not an oral steroid. Indeed, a person of ordinary skill in the art, who reads the Choy *et al.* reference which prohibits the combined use of an anti-IL-6 receptor antibody and a drug other than oral steroid, would not have an apparent reason to use an anti-IL-6 receptor antibody and methotrexate in combination.

Thus, for at least these reasons, applicants respectfully request the rejection be withdrawn.

**CONCLUSION**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

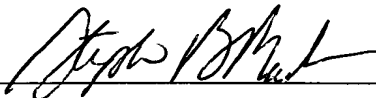
The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741

Respectfully submitted,

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By



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